Long-term Results With the Talent Thoracic Stent Graft in the VALOR Trial

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Objective(s): This report evaluates the 5-year outcomes of thoracic endovascular aneurysm repair (TEVAR) using the Medtronic Vascular Talent Thoracic Stent Graft System (Medtronic Vascular, Santa Rosa, Calif) in patients considered candidates for open surgical repair.

Methods: The Evaluation of the Medtronic Vascular Talent Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms (VALOR) trial was a prospective, nonrandomized, multicenter, pivotal study conducted at 38 sites. Between December 2003 and June 2005, VALOR enrolled 195 patients (mean age, 70.2 ± 11.1 years) who were at low or moderate risk (0, 1, and 2) by the modified Society for Vascular Surgery and American Association for Vascular Surgery criteria. The patients had fusiform thoracic aortic aneurysms (TAA) or focal saccular TAA/penetrating atherosclerotic ulcers, or both. Standard follow-up interval examinations were conducted at 1 month, 6 months, 1 year, and annually thereafter.

Results: At 5 years, freedom from aneurysm-related mortality (ARM) was 96.1%, freedom from all-cause mortality was 58.5%, freedom from aneurysm rupture was 97.1%, and freedom from conversion to surgery was 97.1%. ARM occurred in only one patient after the first year. Four patients were converted to open surgery during the 5 years, 2 due to endoleak, 1 due to aneurysm enlargement, and 1 due to perigraft infection. Four patients experienced aneurysm rupture. From 1 month to 5 years, stent graft migration >5 mm was documented in eight patients. There were eight patients with loss of stent graft integrity, all of which occurred after 2 years. The rate of type I endoleak was 4.6% up to 1 month, 6.3% from 1 month to 1 year, and 3.8% during year 5. The rate of type III endoleak was 1.3% ≤1 month, 1.9% from 1 month to 1 year, and 1.9% during year 5. Through 5 years, 30 patients underwent additional endovascular procedures.

Conclusion: Through 5 years of follow-up in patients who were candidates for open surgical repair, TEVAR using the Talent Thoracic Stent Graft System demonstrated sustained protection from ARM, aneurysm rupture, and conversion to surgery, as well as durable stent graft performance.

Remote Wireless Sensing for Aneurysm Sac Pressure Sac Measurements After Thoracic Endovascular Aneurysm Repair: An Initial Experience and a Midterm Follow-up

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Objective(s): Remote wireless pressure-sensing is a modality used to identify successful aneurysm exclusion after endovascular repair. The efficacy and accuracy of the sensors is promising in detecting endoleak in patients after endovascular aneurysm repair (EVAR). Little evidence exists regarding their utility in thoracic EVAR (TEVAR). This study reported our experience with the EndoSure® system in patients with TEVAR and its role in detecting intraoperative and postoperative endoleak during the aneurysm surveillance.

Methods: This is a retrospective review of the prospectively collected data on eight patients in our aortic registry who underwent TEVAR with EndoSure® device placement.

Results: All grafts and sensors were successfully deployed. Sac pressures were measured before and after TEVAR in the operating room and during follow-up with intravenous contrast computed tomography (CT) scans. Intraoperative type I endoleak was detected in two patients with the EndoSure® system, which were promptly repaired using the extension cuffs. The EndoSure® system also detected three postoperative endoleaks: two distal type I and one retrograde leak via a revascularized superior mesenteric artery (SMA). The endoleaks were initially identified by persistently high sac pressure measurements and further confirmed by CT scans. Both distal type I endoleaks were repaired by extension cuffs, and the retrograde SMA endoleak was repaired by coil embolization of the SMA. Two of the three endoleaks were detected in hybrid TEVAR patients. The aortic sac pulse pressure ratio (ASPPR) in all patients decreased during surveillance, correlating with the CT scan findings and demonstrating a ≥5 mm reduction in aortic diameter in 75% of patients ($P = .009$).

Conclusions: This is one of the few studies reporting the utility of EndoSure system in TEVAR and hybrid TEVAR patients. The EndoSure® system provides useful information for the detection of intraoperative and postoperative type I endoleak in TEVAR and also provides serial follow-up data in patients with type II endoleak. We recommend using this modality only as an adjunct to radiologic imaging in TEVAR patients. The information provided by the EndoSure® System should be interpreted with caution. Larger studies with a long-term follow-up and cost-analysis are required to further define the utility of this modality in TEVAR.

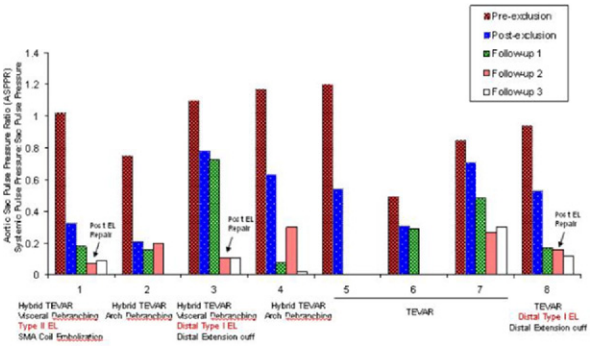

Figure 1: Graphic Representation of Aortic Sac Pulse Pressure Ratio (ASPPR) in eight TEVAR patients; Pre and Post exclusion, during follow up visit and post Endoleak repair

Worse Long-term Outcomes After Endovascular Aneurysm Repair in Patients With Aortoiliac Aneurysms Involving the Iliac Bifurcation: An Opportunity for Iliac Branched Grafts?

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Objective(s): Endovascular aneurysm repair (EVAR) has become the standard treatment of abdominal aortic aneurysms (AAA) and is also commonly used for treatment of aortoiliac aneurysms. However, treatment of aortoiliac aneurysms involving the iliac bifurcation often requires hypogastric artery sacrifice during EVAR, which may result in ischemic complications and buttock claudication. We hypothesized that aneurysmal involvement of the iliac arteries also has a negative effect on the durability of EVAR and sought to determine what fraction of these patients could be candidates for internal iliac artery preservation with an iliac branch graft device (IBG).

Methods: A review of 632 patients who underwent EVAR at a single institution between 2001 and 2010 was performed. Patients were divided into two groups: group 1 included patients who underwent EVAR for treatment of aneurysms that did not involve the iliac bifurcation, and group 2 included patients with aortoiliac aneurysms that involved the iliac bifurcation (diameter >22 mm). Operative details and outcomes were compared between the groups and preprocedural computed tomography (CT) scans of patients in group 2 were used to determine if anatomy was suitable for IBG.